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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,482	09/15/2000	Linda Anne Crofts	1871-130	9624

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EXAMINER

ULM, JOHN D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 10/22/2003

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/509,482

Applicant(s)

CROFTS ET AL.

Examiner

John D. Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 and 30-36 is/are pending in the application.
- 4a) Of the above claim(s) 5-8, 15-18 and 25 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-24, 27, 28 and 30-34 is/are allowed.
- 6) ☒ Claim(s) 1-4, 9-14, 19, 20, 26, 35 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

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1) Claims 1 to 28 and 30 to 36 are pending in the instant application. Claims 1 to 4, 13, 14, 21 to 23 and 26 to 28 have been amended, claim 29 has been canceled and claims 30 to 36 have been added as requested by Applicant in Paper Number 24, filed 15 July of 2003.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 5 to 8, 15 to 18, 25 and 26 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

5) The finality of the last Office action has been withdrawn in view of the granting of the petition under 37 C.F.R. § 1.144 that was filed on 04 June of 2003.

6) Claims 21 to 24, 27, 28 and 30 to 34 are allowable as written.

7) The instant specification does not comply with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. The text in lines 33 and 34 on page 10, 31 and 32 on page 11, and line 12 on page 17 of the instant specification discusses nucleotide and amino acid sequences without employing the required sequence identifiers. Correction is required. See M.P.E.P. 2422.03.

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8) Claims 19 and 20 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A properly dependant claim can not conceivably be infringed without infringing any of the claims from which it depends. See M.P.E.P. 608.01(n)III.

8) Claims 1 to 4, 9 to 14, 19, 20 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention essentially for those reasons of record as applied to 1 to 4 and 9 to 14 in section 9 of Paper number 10. These claims encompass a polynucleotide molecule encoding a human vitamin D receptor isoform and comprising a nucleotide sequence at least 95% identical to "a nucleotide sequence of exon 1d of human VDR gene, or fragment thereof" and antisense molecules thereto. As stated in the original rejection, the only "nucleotide sequence of exon 1d of human VDR gene" which is described in the instant specification in sufficient detail to demonstrate possession is presented in SEQ ID NO:1 of the instant application. Applicant has traversed this rejection on the premise that the instant specification describes a representative number of material embodiments of the genus of molecules encompassed by the instant claims. The instant specification does not describe a

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“**representative**” number of species within the claimed genus. In fact, the instant application does not describe even a single species within the claimed genus which lacks a nucleotide sequence encoding SEQ ID NO:21. Therefore, this is a feature that is common to all of the species within the genus of nucleic acid molecules adequately described in the instant specification but which is not reflected in the instant claims.

9) Claims 1 to 4, 9 to 14, 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention essentially for those reasons of record as applied to claims 1 to 4 and 9 to 14 in section 10 of Paper Number 10. These claims require an isolated polynucleotide which encodes a human vitamin D receptor or which “specifically” hybridizes thereto. Applicant has traversed this rejection upon the premise that the skill level in the art allows one to routinely alter the amino acid sequence of a protein and predict the consequences of that alteration. This is not persuasive because the art of protein biology has actually demonstrated that proteins are substantially more sensitive to amino acid substitutions than Applicant has alleged. Further, the rejection is based upon a proper analysis of this particular art and includes a consideration of the number of working examples of intentionally alter proteins, of which there are none, and guidance as to with residues within the amino acid sequence of the instant invention are critical to the structural and functional integrity of a protein comprising that sequence, of which there are also none. Simply making an unsupported asserting that the art of protein chemistry is predictable

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does not remedy the deficiencies of the instant specification with regard to the breadth of the instant claims.

10) Claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10.1) These claims are vague and indefinite because it is unclear how a nucleic acid that hybridizes to a referenced nucleic acid differs from one that "specifically" hybridizes thereto. Therefore, it is not possible to determine the metes and bounds of a claim which employs this limitation.

10.2) Claim 19 is vague and indefinite because the limitation "high stringency conditions" is conditional and neither the claim nor the instant specification provides the defining conditions.

11) Claims 35 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. These claims are directed to a method of producing a "VDR" polypeptide but the method is not limited to one which employs a nucleic acid encoding a "VDR" polypeptide. The vast majority of polynucleotide molecules encompassed by claims 21 to 23 do not encode anything, much less a "VDR" polypeptide.

12) Applicant's arguments filed 15 July of 2003 have been fully considered but they are not persuasive.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800